PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 9896.143.0

WILLIAMS, ET AL.

Application No.: 09/519,246 Examiner: Thomas C. Barrett

Filed: March 6, 2000 Group Art Unit: 3738

For: ENDOVASCULAR GRAFT COATINGS

AFFIDAVIT UNDER 37 CFR 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

State of Minnesota)
) S.S.
County of Hennepin)

Mr. David L. Clapper, being first duly sworn, deposes and says:

1. I am David L. Clapper. My educational background is as follows: I received a B.S. degree in Zoology from Iowa State University in 1967, an M.A. degree in Biology from the University of Nebraska at Omaha in 1974, and a Ph.D. in Molecular, Cellular, and Developmental Biology from Iowa State University in 1979. I am currently a consultant for SurModics, where I previously worked for 14 years. During my employment at SurModics, I worked for 14 years on development, testing, and commercialization of polymeric coatings. For about 12 years of that time, I worked on development, testing, and commercialization of polymeric coatings on vascular grafts. I also worked for about 2 years on development, testing, and commercialization of polymeric coatings for use on endovascular grafts. While at SurModics I collaborated with and was very familiar with the work of Patrick Guire. Therefore, while working on the subject matter of the present invention I was aware of the various coatings utilized on vascular grafts and

the structures utilized for endovascular grafts, including the vascular grafts disclosed or suggested in the cited Guire reference, United States Patent 4,979,959, and the endovascular graft structure disclosed or suggested in the cited Marin reference, United States Patent 5,433,477.

3. This affidavit is being submitted to explain the unexpected results we have discovered in the endovascular grafts having the thin and conformal hemostatic coatings disclosed or suggested in the present invention in light of the above referenced prior art cited in the Office Action.

4. Concerns about perigraft leaking—leaking around or through an endovascular graft—have limited the use of endovascular graft therapies. The prior art does not show coatings of any type on endovascular grafts to address perigraft leaking. Though endovascular grafts are not known to be coated in the art, clinicians are familiar with reducing through-graft leaking in other grafts by coating them with protein (e.g. albumin, collagen) to physically plug pores in the graft. Such coatings stiffen the graft and thereby reduce pliability. Because the experience of those of ordinary skill in the art of making endovascular grafts, as well as surgeons who install the grafts, has been that the application of coatings to any graft structure to reduce through-graft leaking reduces the pliability of the graft, it is not surprising that prior to this invention endovascular grafts were not coated to attempt to reduce perigraft leaking. Therefore, those of skill in the art would expect that an endovascular graft coated with coatings known in the art to reduce leaking could not be safely fed through a blood vessel to the location in need of repair due to the rigidity caused by the coating. Furthermore, those of skill in the art also believed that because endovascular grafts are installed within a blood vessel, particularly vessels having smaller diameters, problems may arise including the increase of turbulence in the blood flow within the vessel, and potential unacceptable thrombotic response that may restrict blood flow, narrow the vessel lumen and possibly occlude the vessel over time. Therefore, it was counterintuitive to those of ordinary skill in the art to consider putting a hemostatic coating on an endovascular graft because of these concerns related to the pliability of the coated graft and the possibility of the previously described problems that may occur due to a hemostatic response at the graft site.

5. The endovascular graft coatings of this invention effectively reduce perigraft leaking, and surprisingly do so without an unacceptable reduction in pliability of the coated graft material. Therefore, the endovascular graft of the present invention is not restricted by rigidity when guided through a blood vessel during administration and is less likely to experience leaking after installation. Nothing in the cited art discloses or even suggests endovascular grafts coated with a hemostatic coating to reduce perigraft leaking that remain pliable enough to be fed through a blood vessel on a guide wire. Furthermore, nothing in the cited art discloses or suggests the structure or potential use of an endovascular graft coated with a hemostatic agent that is intended to be implanted within the lumen of a vessel. In fact, during the development of vascular grafts such as those described in Guire, much attention was paid to developing coatings that promoted cell growth and an antithrombogenic (non-hemostatic) surface in a small diameter graft (See Example 1). A person of ordinary skill in the art having access to Guire would likely find it counterintuitive to apply a hemostatic coating to an endovascular graft due to some or all of the main concerns identified above.

6. In conclusion, Applicants unexpectedly discovered that coating an endovascular graft with a thin and conformal hemostatic coating using Applicants' processes unexpectedly enhanced the prevention of endoleaking around or through the graft while still maintaining acceptable pliability and limiting the unacceptable risk of damaging thrombosis at the graft site. This discovery is counterintuitive to the consensus against coating endovascular grafts, and moreover coating endovascular grafts with hemostatic coatings, and therefore would not be obvious to a person of ordinary skill in the art in view of the cited references. Based upon these findings, the research, which is the subject of the presently pending application, has shown the unexpected value of these coatings on endovascular grafts.

David L. Clapper

Subscribed and sworn to before me
this 4th day of October, 2005.

JULIE A BOLLIG
Notary Public
Minnesota
My Commission Expires January 31, 2009

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